IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
Rault et al.
APPLICATION NO: 10/572,687
FILED: August 8, 2006
FOR: Coated Tablets

Art Unit: 1618
Examiner: Nissa M. Westerberg
Confirmation No.: 4963

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BRIEF ON APPEAL

Sir:

This brief is in furtherance of the Notice of Appeal, filed in this case on September 14, 2010.

The fees required under 37 C.F.R. are dealt with in the accompanying Transmittal of Appeal Brief.

I. REAL PARTY IN INTEREST

The real party of interest in this appeal is Novartis Consumer Health S.A. by an unrecorded assignment executed by the applicants of the present application on March 10, 2006.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

1. Claims cancelled: 1-16.
2. Claims withdrawn from consideration: none.
3. Claims pending: 17-24; all rejected and on appeal.
4. Claims allowed: none.

IV. STATUS OF AMENDMENTS

After the Final Rejection, no amendment has been filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There are three independent claims: 17, 21, and 24.

The subject matter of claim 17 is a film coated tablet consisting essentially of (a) a core in which the only pharmaceutically active substance is diclofenac or salt thereof and (b) a single film coating comprising four ingredients (page 2, para. 4; page 3, Example 1).

The subject matter of claim 21 is a film coated tablet, as above, wherein the tablet core comprises microcrystalline cellulose (page 2, para. 4; page 3, Example 1; claim 5).

The subject matter of claim 24 is a film coated tablet consisting of a core consisting essentially of eight ingredients and a film coating comprising four ingredients (page 3, example 1).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are various grounds for rejection:

1) Claims 17-23 are rejected under 35 USC 112 for failing to comply with the written description requirement because they recite new matter.

2) Claims 17-23 are rejected under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701") in view of DeHaan, US 2006/0051420 ("US'420") and the SEPTIFILM® product page ("SEPTIFILM").

3) Claims 17-23 are rejected under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701"), DeHaan, US 2006/0051420 ("US'420") and the SEPTIFILM® product page ("SEPTIFILM") and further in view of Gimet USP 5,601,843 ("US'843").

4) Claims 17-23 are rejected under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701"), DeHaan, US 2006/0051420 ("US'420") and the SEPTIFILM® product page ("SEPTIFILM") and further in view of Humbert-Droz USP 6,083,531 ("US'531").

5) Claim 24 is rejected under 35 USC 103 as obvious over Gimet USP 5,601,843 ("US'843"), in view of Humbert-Droz USP 6,083,531 ("US'531"), Voss USP 5,690,927 ("US'927"), DeHaan, US 2006/0051420 ("US'420") and the SEPTIFILM® product page ("SEPTIFILM").

VII. ARGUMENTS

REJECTION UNDER 35 USC 112

Claims 17-23 are rejected under 35 USC 112 for failure to comply with the written description requirement. The rejection is traversed. The Examiner argues that since the exclusion of other actives is not specifically recited in the specification, recitation of only one active in the claims was not described in the specification so as to reasonably convey that the inventors had possession of the invention at the time of filing and therefore introduces new matter (stated to be a new "concept" by the Examiner). The Examiner has requested support for the recitation of a single pharmaceutically active substance limitation and has been directed to the entire specification in support. The specification is directed solely to a single-active tablet. Specifically, page 2, lines 13 and 14 recite "diclofenac ... is the only pharmaceutically active substance present". Nowhere is there a teaching or suggestion that a second active be incorporated into said tablet.

However, the Examiner argues on the ground that other compounds recited in the specification, specifically starch and lactose, "exert an effect on the body" and thus are pharmaceutically active. Applicants traverse. Exerting an effect on the body is not the criterion by which a pharmaceutical is defined. There are many compounds which "exert an effect" on the body; however, such compounds are not recognized as pharmaceuticals. One could include among these table salt and water (both of which have an effect on the body and are critical to human life), and even sunlight, which among other effects produces vitamin D in the body. Thus, merely affecting the body does not define whether or not something is pharmaceutically active as that term is commonly used in the pharmaceutical arts. Furthermore, by definition, claims 17-23 recite that diclofenac is the sole active in the tablet. Thus, even if one were to accept the Examiner's broad definition, such definition is not relevant to these claims. That diclofenac is the sole active is specifically recited in the specification as filed and does not constitute new matter.

REJECTIONS UNDER 35 USC 103

1) The rejection of claims 17-23 under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701") in view of DeHaan, US 2006/0051420 ("US'420") and the SEPTIFILM® product page ("SEPTIFILM") is traversed.

There are various issues wherein applicants and the Examiner are in disagreement.

The first of these is the scope of the claims. Applicants have limited the scope by use of the limiting expression "consisting essentially of". The Examiner rejects this terminology and reads the claims broadly as "comprising", based on the guidelines of MPEP 2111.03. The Examiner's attention has been directed to the entire specification, from which it is clear what the basic and novel characteristics of the claimed compositions are: a tablet with a single active ingredient which is surrounded by a single film coating. For the Examiner to insist that the claims read on more than this or that this is not clear from the specification is without merit. Consistent with her position, the Examiner argues that removal of a second active (tramadol) from US'701 is not required by the present claims or that the addition of the second active in a separate core does not materially affect the administration of the tablet. Only the improper re-drafting of the claims by the Examiner can support such statements. Per the MPEP the phrase "consisting essentially of" is interpreted to exclude that which materially affects the basic and novel characteristics of the invention. Here the phrase clearly excludes the teachings of US'701, since this reference requires a second active ingredient in a second core which is separated from the core containing applicants' active. Thus, there is not only a material structural difference from the multilayer tablet of the reference and that of the present invention but the exclusion of tramadol eliminates the numerous side effects associated with the use of tramadol. These side effects include constipation, dizziness, and nausea. To say that there is no material effect from the inclusion of this second active is without medical basis. *Contra* to the Examiner's position, the inclusion of this second active does materially affect the administration of the tablet to a patient. The Examiner's reference here to starch and lactose is traversed for the reasons provided above; they are not pharmaceuticals. The Examiner argues that material effects are not necessarily medical effects - - which is true. The material effects may be many. However, medical effects, such as eliminating possible serious side effects by excluding a second active, is certainly a material effect. The inclusion of tramadol in applicants' tablet would materially change the characteristics of the invention. It is deemed that the refusal of the Examiner to examine the claims as they are presented and not as she has redrafted them is error.

The Examiner's creative definition of a "separating" layer, which she equates to applicants' film coating is also traversed. The teaching of US'701 with regard to a separating layer is irrelevant to the present invention. US'701 teaches a multilayer (minimum of three layer) tablet with two active ingredients and an internal separation layer. This layer is quite different from a coating. Coatings are mentioned only in passing in US'701 as optional embodiments. The Examiner has dismissed the distinction between a coating and a separation layer on the basis that their

compositions and not their labels must be evaluated. Applicants disagree that compositions alone are relevant. The "labels", 'coating' and 'separation layer', are not merely names in either the reference or in the present application. Rather, these terms define the positions and functions of these moieties. In the present application, since there is only one core moiety, a "separation layer" would be a meaningless term and is not used. In the case of US'701, the reference recites both a separation layer and a coating and the reference itself distinguishes between the two as to both composition and function. In US'701 the separation layers are positioned between the layers of actives in the core and function to separate the active-compound-containing layers from each other without, however, impairing their release profiles upon oral administration (col., 1, lines 50-64). Controlled release of the actives is taught to be achieved by a suitable "retard coating" which can be made from water-insoluble waxes or polymers. The "retard layer" may additionally itself comprise "non-retarded" (*sic*) polymers to modify the release rate of the actives and may also be coated by additional coatings (col. 4, lines 4-32). The retard layer never comprises non-retarded polymers alone. There is no teaching or suggestion in US'701 to coat the core of a tablet containing a single active with a single coating comprising 60-70% (w/w) hydroxypropyl methylcellulose, 8-12% (w/w) stearic acid, 5-15% (w/w) microcrystalline cellulose, and 10-20% (w/w) titanium dioxide, as in the present claims. Since the reference itself distinguishes between the separation layer and the coatings, the Examiner cannot contradict the teaching therein and equate the two. The composition of one has no relevance to the composition of the other. Nothing that the reference teaches about the composition of the separation layer can be transferred to the coatings. Furthermore, even if the teaching regarding the separation layer could be applied to the coating, the amounts of disclosed components such as MCC and HPMC are completely outside the scope of the corresponding compounds of the present invention. The Examiner herself recognizes the limited relevance of US'701 by stating that the reference does not teach diclofenac in the core, that it does not teach that the diclofenac-containing layer is coated, and that the reference does not teach stearic acid. Notwithstanding these significant differences between US'701 and the present invention, the Examiner nevertheless concludes that it would be obvious "to prepare a tablet with more than 3 layers or with diclofenac in the core" to arrive at a coated diclofenac tablet. This conclusion is totally without basis in the reference.

The Examiner argues that a coating can be a separating layer because the coating can separate the tablet from the external environment. By this logic, an uncoated tablet packaged in a sealed bottle would be prior art because the sealed bottle separates the tablet from the environment. Thus, a sealed bottle qualifies as a separating layer by the Examiner's definition.

However, words must be interpreted using their ordinary definitions unless an alternative meaning is clearly intended. Here there is no basis for creative definitions. Reading the art and the instant claims using the ordinary definitions of the terms therein, the difference between the art and the claims is clear. The Examiner's response to this is that bottle analogy would only apply if the bottle wall comprised applicants' components (HPMC, stearic acid, etc.) This misses the point. A bottle whose wall contained these components would still not be understood to be a "film coating" and an uncoated tablet inside such a bottle would still not be understood by those in the art to be a "film coated tablet".

The Examiner argues that applicants have not presented evidence that her definition of a separating layer is contrary to the ordinary definition of the term. Applicants traverse. As discussed above, the very reference cited by the Examiner distinguishes between a separating layer and a coating, both as to composition and function. The Examiner cannot conflate these two distinct meanings for purposes of rejecting under 35 USC 103.

The MPEP recites criteria which the Examiner should adhere to in making a case for *prima facie* obviousness. These include, but not limited to: 1) identifying the motivation found in the art to make the invention; 2) evaluating the art from the standpoint of one of ordinary skill in the art; 3) determining whether one of ordinary skill would be motivated to make the invention (i.e., to actually select the claimed subject matter from the art's genus; 4) considering the preferred species taught in the art; 5) considering the number of variables which must be selected from the art to make the invention; and 6) specifically articulating what teaching or suggestions in the art would have motivated one of ordinary skill to select the claimed species or subgenera. Finally, MPEP 2144.08 states that conclusory statements without articulated rationale or evidentiary support do not constitute sufficient factual findings. Without these, it is deemed that there is no basis for the Examiner's rejection based on obviousness. It is deemed that the Examiner has not met the burden of proof necessary for a rejection under 35 USC 103.

Stating that hardness and compressibility (neither of which, the Examiners agrees, is recited in the art or specification) are known to one of ordinary skill in the art does not support the rejection. (In response to the Examiner's assumption, she has referred to these properties not only in the Actions dated April 24, 2009 and September 23, 2009 but also in that of September 12, 2008.) The search for improving these qualities is merely an open invitation to experiment without guidance. However, since these properties are not taught in the art of record, they do not even reach the level of an invitation to experiment. There is the more fundamental question of what exactly is to be manipulated, since the Examiner starts with the four components in the coating which are disclosed

by the inventors and not by the art. This is pure hindsight reasoning: 1) start with that which the inventors have disclosed, 2) find this in one or more pieces of art, 3) choose those pieces of the art which are part of the invention, and 4) combine them in the inventors' amounts on the basis that "optimization" is something one of ordinary skill in the art would do.

Regarding applicants' argument that DeHaan teaches away from the presently claimed type of coating, the Examiner replies that the mere disclosure in the art of more than one alternative is not a teaching away. That may be so but is not relevant to the situation here. US'420 teaches a dosage form wherein the degradation of an active compound is delayed by use of a "wrap" coating, which may be a film, but is preferably a sugar or sugar film coating (abstract). Within the non-preferred genus "film" are listed a large number of film materials. It is taught that not all of the film materials have the desired stabilizing effect (**[0013]**). Thus, the Examiner's argument is that it would be obvious to one of ordinary skill in the art to select, without undue experimentation, a film to be chosen from a genus of less desirable films, after being made aware that some of these less desirable films are ineffective for stabilizing the active ingredient in US'420. It is deemed by applicants that one of ordinary skill in the art, having been advised that films are less desirable and that certain films are ineffective with regard to the active ingredient in US'420, would prefer to not use any of the less desirable films. It is rather more likely that said person would select a sugar or sugar film coating, all of which function well with the active compound of the reference and, thus, would appear to be more likely to succeed if applied to another active; i.e., the reference teaches away from the coating of the present invention. Thus, and *contra* to the Examiner's position, there no "reasonable expectation of success" from the use of these less desirable films. SEPTIFILM adds nothing to the Examiner's argument, since it only teaches that certain films were known in the art; i.e., that which is known from the specification (see Example 1).

2) The rejection of rejection of claims 17-23 under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701"), DeHaan, US 2006/0051420 ("US'420"), and the SEPTIFILM® product page ("SEPTIFILM") and further in view of Gimet USP 5,601,843 ("US'843") is traversed.

Comments regarding the three primary references are provided above and incorporated herein. The relevance of US'843 to the present invention is remote and adds nothing to the Examiner's arguments. US'843 teaches a tablet which comprises a core which contains an NSAID, said core encapsulated by a coating which contains a prostaglandin whose purpose is to counteract

the possible side effects of the NSAID. The core and coating may be separated by an intermediate coating. *Contra* to the instant claims, which contain a single active in the core and no active in the coating, US'843 teaches a core covered by possibly four coatings, the outermost one of which (the mantle) contains a second active, whose purpose is to counteract the effects of the core. The coatings are described as enteric, aqueous enteric, overcoat, and mantle. Each of these has a different purpose and composition from the others. No one of them suggests the single film coating of the instant invention. The combination of these four references cannot be said to make obvious the instant claims.

The Examiner's response to the arguments above is that applicants have not argued why the teachings of Gimet as to the amount of MCC in the core are not applicable to the claims. Applicants disagree. Gimet is so remote from the present invention that the teaching therein of MCC is not material to the patentability of the present invention. This is even more so since it is cited merely to supplement three other references whose failings are not fixed by the addition of a teaching regarding MCC in the core.

3) The rejection of claims 17-23 under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701"), DeHaan, US 2006/0051420 ("US'420"), and the SEPTIFILM® product page ("SEPTIFILM") and further in view of Humbert-Droz USP 6,083,531 ("US'531") is traversed.

Comments regarding the three primary references are provided above and incorporated herein. The relevance of US'531 to the present invention is remote and adds nothing to the Examiner's arguments. US'531 teaches a tablet which consists of an uncoated mixture of all the ingredients (col. 3, lines 39-44), i.e. one or more actives in combination with fillers, binders, and auxiliaries. The lack of coating is understandable, since the purpose of the composition is to be fast dissolving when placed in the mouth. The combination of these four references cannot be said to make obvious the instant claims.

The Examiner's response to the arguments above is that applicants have not argued why the teachings of US'531 as to the amount of diclofenac are not applicable to the claims. Applicants disagree. US'531 is cited solely for its teaching of a 12.5 mg dosage of diclofenac potassium. As argued above, the Examiner has cobbled together various teachings, broadened applicants' claim scope, and argued that the claims are obvious because the various ingredients of the claimed tablet can be manipulated by one of ordinary skill in the art to arrive at the present invention. Diclofenac is a known, widely-used anti-inflammatory. That US'531 teaches it as one of a multitude (18 are

generically cited at col.2, lines 28-34) in a solid pharmaceutical dosage form is not material to the patentability of the present invention. This is even more so since it is cited merely to supplement three other references whose failings are not fixed by the addition of a teaching regarding a 12.5 mg dosage.

4) The rejection of claim 24 under 35 USC 103 as obvious over Gimet USP 5,601,843 ("US'843"), in view of Humbert-Droz USP 6,083,531 ("US'531"), Voss USP 5,690,927 ("US'927"), DeHaan, US 2006/0051420 ("US'420"), and the SEPTIFILM® product page ("SEPTIFILM") is traversed.

Comments regarding four of these references are provided above and incorporated herein. Regarding Voss, this reference teaches a coated tablet containing two actives, one of which is codeine. As pointed out above with regard to tramadol, codeine is an active with many known undesirable side effects. To say that there is no material effect from the inclusion of this second active (which the Examiner must in order to support this rejection) is without medical basis. (The Examiner has not responded directly to this issue of material effect, except to argue that codeine is not excluded from the claims. See below.) Besides the arguments already made that these references either singly or in combination do not suggest the tablet of the instant invention, it is also strongly suggested by the Examiner's need to reply on five references to attempt to craft an obviousness rejection, that she has merely picked bits and pieces, in hindsight, from a large assemblage of references. Such hindsight collecting cannot be the basis for a rejection under 35 USC 103.

The Examiner's response is that applicants have not met the burden of establishing that codeine is excluded from the claims. Applicants traverse. Codeine is excluded because of the limiting phrase "consisting essentially of", as argued above. In the response, the Examiner refers to prostaglandins which are contained in the coating of Gimet, from which she concludes that Voss is not the only reference containing relevant teachings regarding the composition of the core. It is not understood by applicants what the prostaglandins in Gimet's coating has to do with claim 24. Regarding the use of five references, the Examiner argues that these are justified because of the number and amounts of ingredients in claim 24. This misses the point, which is that the Examiner could only have gathered these references by using applicants' disclosure (hindsight reasoning). Applicants disagree that any judgment on obviousness is necessarily a reconstruction based on hindsight. That the various elements which constitute the tablet of claim 24 can be found in the art

is not in dispute. Applicants have not claimed the novelty of these elements. That their various uses have been disclosed in the art, as the Examiner has argued on pages 12-14 of the September 23, 2009 Action, is not in dispute. But what is argued is that but for applicants' disclosure of a unique combination of these chosen elements in the disclosed amounts to form a novel, useful, and inventive tablet, no person of ordinary skill in the art would have searched for these references, culled them for applicants' disclosed elements, selected the specific amounts of each, and then created the claimed tablet.

VIII. CLAIMS APPENDIX

LISTING OF THE CLAIMS:

Claims 1 – 16 (cancelled)

Claim 17. (Previously presented) A film coated tablet consisting essentially of
(a) a tablet core comprising only one pharmaceutically active substance, which is diclofenac or a pharmaceutically acceptable salt thereof, and
(b) a single film coating comprising 60-70% (w/w) hydroxypropyl methylcellulose, 8-12% (w/w) stearic acid, 5-15% (w/w) microcrystalline cellulose, and 10-20% (w/w) titanium dioxide based on the weight of the coating alone.

Claim 18. (Previously presented) A film coated tablet of claim 17, wherein the tablet core comprises diclofenac potassium.

Claim 19. (Previously presented) A film coated tablet of claim 18, wherein the diclofenac potassium is present in an amount of 10-50 mg.

Claim 20. (Previously presented) A film coated tablet of claim 18, wherein the diclofenac potassium is present in an amount of 12.5 mg.

Claim 21. (Previously presented) A film coated tablet of consisting essentially of
(a) a tablet core comprising only one pharmaceutically active substance, which is diclofenac or a pharmaceutically acceptable salt thereof, and
(b) a single film coating comprising 60-70% (w/w) hydroxypropyl methylcellulose, 8-12% (w/w) stearic acid, 5-15% (w/w) microcrystalline cellulose, and 10-20% (w/w) titanium dioxide based on the weight of the coating alone;
wherein the tablet core comprises microcrystalline cellulose.

Claim 22. (Previously presented) A film coated tablet of claim 21, wherein the microcrystalline cellulose is present in the tablet core in an amount of 2-15% (w/w) of the tablet core.

Claim 23. (Previously presented) A film coated tablet of claim 22, wherein the microcrystalline cellulose is present in the tablet core in an amount of 5-10% (w/w) of the tablet core.

Claim 24. (Previously presented) A film coated tablet which consists of:

(a) a tablet core consisting essentially of:

diclofenac K	12.5 mg
magnesium stearate	2.025 mg
povidone	4.05 mg
silica colloidal anhydrous	8.025 mg
microcrystalline cellulose	13.5 mg
sodium starch glycolate	26.7 mg
lactose monohydrate	33.45 mg
maize starch	99.75 mg; and

(b) a single film coating comprising 60-70% (w/w) hydroxypropyl methylcellulose, 8-12% (w/w) stearic acid, 5-15% (w/w) microcrystalline cellulose, and 10-20% (w/w) titanium dioxide based on the weight of the coating.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

In view of the arguments, it is requested that the Board reverse the Examiner's rejection of all the claims and that the case be passed to issue.

Respectfully submitted,

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